

K203539 Unico Global level 3 Surgical Gown (Film-reinforced SMS), Unico Global Level 3 Surgical Gown (PP+PE)Dec 10, 2021
372 days to decisionK203539 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k203539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 3, 2020
Decision date	Dec 10, 2021
Days to decision	372 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unicoglobal, Inc.
Location	Seongnam, KR
Contact	Yoonsok Park
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203539/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026